AWARD NUMBER: W81XWH-14-2-0007

TITLE: Early Intervention to Reduce Alcohol Misuse and Abuse in the Ohio Army
National Guard

PRINCIPAL INVESTIGATOR: Joseph R. Calabrese, MD

CONTRACTING ORGANIZATION: Case Western Reserve University
                                                Cleveland, OH 44106

REPORT DATE: Sep 2016

TYPE OF REPORT: Annual

PREPARED FOR: U.S. Army Medical Research and Materiel Command
                              Fort Detrick, Maryland 21702-5012

REPORT DOCUMENTATION PAGE

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Early Intervention to Reduce Alcohol Misuse and Abuse in the Ohio Army National Guard	
	5b. GRANT NUMBER
	W81XWH-14-2-0007
	5c. PROGRAM ELEMENT NUMBER

6. AUTHOR(S)	5d. PROJECT NUMBER
Joseph R. Calabrese, MD; Frederic Blow, MD	
	5e. TASK NUMBER
	5f. WORK UNIT NUMBER
E-Mail: joseph.calabrese@uhhospitals.org	

7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)	8. PERFORMING ORGANIZATION REPORT NUMBER
Case Western Reserve University 10900 Euclid Ave. Cleveland, OH 44106-1712	

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12. DISTRIBUTION / AVAILABILITY STATEMENT

Approved for Public Release; Distribution Unlimited

13. SUPPLEMENTARY NOTES

14. ABSTRACT

The proposed project is a fully-powered randomized controlled trial of a Web-based + texting alcohol brief intervention (WT-BI) versus an Enhanced Usual Care (EUC) condition for National Guard members in the State of Ohio who meet criteria for at-risk drinking in the previous 3 months. After tailoring the content of the WT-BI intervention for NG soldiers, the proposed study will screen ~ 3,100 individuals over the three year enrollment period as part of the larger ongoing longitudinal assessment of ONG members in the OHARNG MHI, to identify 750 participants with at-risk drinking. These ONG members will be randomized to either the WT-BI (n=375) or the EUC condition (n=375) and followed for one year. Enrollment has not yet begun, therefore there are no results to report at this time.

15. SUBJECT TERMS

Ohio National Guard, Mental Health, Alcohol Use Disorders, Risky alcohol use, SBIRT (Screening, Brief Intervention, Referral to Treatment) model, Risky

16. SECURITY CLASSIFICATION OF:			17. LIMITATION OF ABSTRACT	18. NUMBER OF PAGES	19a. NAME OF RESPONSIBLE PERSON USAMRMC
a. REPORT	b. ABSTRACT	c. THIS PAGE	UU	33	19b. TELEPHONE NUMBER *(include area code)*
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Standard Form 298 (Rev. 8-98)
Prescribed by ANSI Std. Z39.18

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1. **INTRODUCTION:** Narrative that briefly (one paragraph) describes the subject, purpose and scope of the research.

   This project is a fully-powered randomized controlled trial of a mobile phone app - and text-based alcohol brief intervention (MT-BI) versus an Enhanced Usual Care (EUC) condition for National Guard members in the State of Ohio who meet criteria for unhealthy drinking in the previous 3 months. After tailoring the content of the MT- BI intervention for National Guard soldiers, the proposed study will screen ~ 3,100 different individuals over the three year enrollment period as part of the larger yearly ongoing longitudinal assessment of ONG members enrolled in the Ohio Army National Guard Mental Health Initiative (OHARNG MHI), to identify 750 participants with unhealthy drinking. These Guard members will then be randomized to either the MT-BI (n=375) or the EUC condition (n=375) and followed for one year post-enrollment.

   The specific aims are to compare MT-BI and EUC in:
   1. Reducing the frequency and intensity of at-risk drinking at 3 -,6- and 12-months;
   2. Decreasing binge drinking at 3-, 6- and 12 months.
   The secondary aims are to:
   1. Compare the MT-BI and EUC conditions in reducing the frequency of illicit drug use and depressive symptoms at 3-, 6- and 12-months;
   2. Examine if deployment status moderates the effect of intervention assignment (MT-BI or EUC) on post-intervention drinking, depressed feelings, and other substance use.

2. **KEYWORDS:** Provide a brief list of keywords (limit to 20 words).

   Alcohol screening, brief intervention, drinking, military, eHealth, mHealth, social support

3. **ACCOMPLISHMENTS:** The PI is reminded that the recipient organization is required to obtain prior written approval from the awarding agency Grants Officer whenever there are significant changes in the project or its direction.

   What were the major goals of the project?

   Task #1: Customize mobile phone app – and text-based alcohol brief intervention for National Guard (NG) population
   Subtask 1
   Facilitate focus groups, consisting of Ohio NG leadership and soldiers to develop, refine, and tailor the screening questionnaires, assessments, and risk management procedures.
   Subtask 2
   Create mobile phone app – and text-based alcohol brief intervention program and a project management tracking system in the first 9 months of Year 1.

   Task #2: Data Collection
   Subtask 1
   Hire (as necessary) and train all study personnel in Year 1, with ongoing trainings held each year as needed.

Subtask 2
Starting in the 4th quarter of Year 1 through Year 4, enrollment of up to 750 participants (~250 participants/year over 3 years) utilizing the Ohio Army National Guard Mental Health Initiative platform for recruitment
Subtask 3
Participant follow-up at 3, 6, and 12 months through Year 5 (N=750)

Task #3: Data Dissemination
Subtask 1
Starting in Year 2, performance of descriptive analysis of the data including, but not limited to hazardous alcohol use and deployments, and hazardous alcohol use with co-morbid illnesses, i.e. PTSD, depression.
Subtask 2
Upon completion of data collection, at least 1 submission to a peer-reviewed journal will be derived from the study data
Subtask 3
Starting in Year 2, presentations each year of the most recent alcohol data, i.e. at advisory board meetings, poster/symposium presentations at scientific conferences, and presentations for the Ohio NG, as requested.

Task #4: Oversight Meetings
Subtask 1
External Scientific Advisory Board, providing critical feedback on the scientific merit of the project, will be held once annually, Years 1-5.
Subtask 2
Administrative Advisory Board, providing guidance on non-scientific issues, will be held once annually, Years 1-5.
Subtask 3
Sponsor Scientific Meeting (as requested) consisting of programmatic and scientific leaders to provide a scientific and fiscal update.
Subtask 4
Data Safety Monitoring Board, provide information as needed to the quarterly DSMB meetings, held by the Coordinating Center

Task #5: Regulatory & Reporting
Subtask 1
Initial Submission in Year 1, Continuing Reviews in Years 2-5, and addendum submissions as needed, to applicable local IRBs of record
Subtask 2
Obtain Certificate of Confidentiality from DHHS in Year 1
Subtask 3
Initial Submission in Year 1, Continuing Review in Years 2-5, and applicable submissions to the DoD Office of Research Protections
Subtask 4
Quarterly financial reporting to USAMRAA, as required, in Years 1-5

Annual progress report to USAMRMC in Years 1-4, with a Final Report at the end of Year 5.

Subtask 6
Progress reports to sponsoring agency (as requested)

What was accomplished under these goals?

Task #1: Customize mobile phone app – and text-based alcohol brief intervention for National Guard (NG) population – 90%

Weekly development meetings are occurring with the University of Michigan Center for Health, Communications, and Research (CHCR), the group programming the phone app. The specific features of the app were decided upon and developed including:
- The brief intervention, which includes setting goals, identifying strengths, answering questions on past 30 days use of alcohol, fitness and stress, identifying benefits and reviewing a testimonial and an introduction to how the app may be useful to the participant
- Trackers for daily alcohol use, physical activity and stress
- Weekly planners that can assist them in using tools to reduce their drinking and meet daily goals.
- The ability to customize the frequency with which tips related to alcohol, stress and fitness are sent to the user
- A place for study staff to post news articles and videos about alcohol, fitness and stress, with the ability to add comments in order to help fellow guardsmen, and communicate with a health coach.
- A place for participants to discuss issues with a health coach related to alcohol, fitness and stress
- Participants will be able to earn coins for using different features of the app. The amount of coins earned for different features has been finalized, for every 100 coins earned the participant will receive a dollar. Each feature will have a tutorial the first time that you use the feature to increase usability.
- UM staff and CHCR have completed the intro video which will be posted on the app stores.

The following meetings took place between study staff and OHARNG members:
- On January 6, 2016 a meeting was held with the (Ohio Army National Guard) OHARNG Resilience, Risk Reduction, and Suicide Prevention (R3SP) Coordinator as well as the OHARNG Alcohol and Drug Control Officer and 3 OHARNG Prevention Coordinators. At this meeting, an overview of the project was given, as well as updates on the current status of the app and intervention development process. The OHARNG representatives that attended the meeting had a favorable view of the project and noted that they are happy to assist in any way possible to help this study be successful. They provided helpful insights and ideas for retention.
- On March 14, 2016 the Project Manager at UM traveled to Columbus, OH for the first meeting of the focus group. This meeting was attended by the Ohio Army National Guard

(OHARNG) Resilience, Risk Reduction, and Suicide Prevention (R3SP) Coordinator, one of the OHARNG Prevention Coordinators and 3 members of the OHARNG. At this meeting, the Project Manager provided an overview of the study, including the background/rationale, the design and methodology of the study and study progress as of that date. She also got their feedback on the first iteration of the BI and the overall look and feel of the app.

- A second focus group meeting was held May 12, 2016. This meeting was attended by the OHARNG R3SP Coordinator, the OHARNG Alcohol and Drug Control Officer and 5 OHARNG soldiers. At this meeting the study team received feedback on the development of the app to date, including changes based on the feedback they provided in March. The OHARNG representatives that attended the meeting continue to have a favorable view of the project and noted that they are happy to assist in any way possible to help this study be successful. They provided helpful insights in to what the app looks like and the utility of the app for their fellow Guardsman.

UM staff completed the Invention Report Form and submitted to their technology transfer office. The form was required for licensing purposes and was one of the steps required to get the app posted on app stores.

Task #2: Data Collection – 10% completed
Over the past year the list of assessments to be used in the study was finalized and the data coordinator programmed assessments in to REDCap, the electronic data capture system that is being used for this study. Over the past month, study team members, including the project managers at UHCMC and at UM, as well as the study coordinator at UHCMC have been testing the database and suggesting edits and refinements to the data coordinator.

The coordinating site has been working on a manual of procedures that will be used to train study staff. This manual will include details on how to navigate the REDCap data, how potential subjects will be identified by the platform survey firm, Abt SRBI, and then pre-screened by study staff at UHCMC and UM, how to complete specific forms within the database, how data management and quality assurance will be done for the study and details on the safety/triage protocols for participants who endorse suicidal ideation either on the phone or in their online survey has been completed.

In addition, The University of Toledo has posted a position for study coordinator and are in the process of interviewing/hiring.

Task #3: Data Dissemination – 0% completed
There were no activities related to this task completed over the reporting period.

Task #4: Oversight Meetings – 26% completed
Dr. Blow attended the Joint Army/NIH Substance Abuse IPR, which was held September 29, 2015 – October 1, 2015. A summary of his presentation is as follows:

1. **Research Questions & Hypotheses**
   a. AIM 1: Compare the Smartphone (SP)-BI and EUC conditions in reducing the frequency

and intensity of at-risk drinking at 3, 6, and 12 months post-intervention.

    i.   Hypothesis: Participants randomized to the SP-BI condition will report significantly fewer days/week drinking and fewer drinks/day than participants in the EUC condition at follow-ups.

b.   AIM 2: Compare the SP-BI and EUC conditions for binge drinking at 3-, 6- and 12 months.

    i.   Hypothesis: Participants randomized to the SP-BI condition will report significantly fewer binge drinking episodes compared to the EUC participants at follow-ups.

c.   Secondary AIM 1: Compare the SP-BI and EUC conditions in reducing the frequency of illicit drug use and depressive symptoms at 3-, 6- and 12 months.

    i.   Hypothesis: Participants randomized to the SP-BI condition will significantly reduce the frequency of illicit drug use compared to participants in the EUC condition.

d.   Secondary AIM 2: Examine the impact of the interaction of deployment status with intervention condition (SP-BI or EUC) on 3-, 6- and 12-month measures of alcohol and drug use.

    i.   Hypothesis: NG members who have been deployed in OEF/OIF/OND are expected to have higher risk of at-risk drinking compared to those who have not been deployed. We hypothesize that individuals who have been deployed will be less likely to change their drinking than those who have not been deployed. However, the web-based program will address individual concerns and issues related to deployment.

2. **Design & Methodology**

a.   Given the rapidly changing mobile health field, with dramatic increases in the use of smartphone technologies, we are developing and testing an eHealth mobile phone app for delivery of intervention content, and for providing real-time feedback and support for drinking goals. This real-time feedback component will provide a unique platform for delivery of intervention content and follow-ups.

b.   The smartphone mobile app will include a section on safe rides to prevent drinking and driving.

c.   One of the strengths of this project is that we will have access to detailed information collected in the longitudinal cohort that has been followed for several years, including extensive assessments that were conducted prior to and post-deployment (Calabrese; Ohio Army National Guard Mental Health Initiative). Thus, the Ohio-based DOD study will have the ability to examine moderators including impact of deployment and development of comorbid mental disorders

3. **Methodology**

a.   On a population basis, SBIRT approaches can have a meaningful impact on the hazardous use of alcohol and other substances.

b.   Engagement and adherence have been a limiting factor in previous attempts to apply population based approaches to hazardous use of alcohol and other substances, including in military populations.

c.   Smartphone apps have many advantages over other approaches:

    i.   Allows for and encourages frequent short interactions with the subject – the phone is in many ways an extension of the person and his/her social milieu – it is always

there with you.

    ii. At all times a graphically appealing and simple dashboard of icons will be available, without any prompts. For example, for a particular subject who identified strategies to limit drinking (e.g. diluting drinks, alternating alcohol and non-alcohol drinks, setting a limit and sticking to it, etc.) there would be a "drinking strategies" icon on his dashboard.

4. **Anticipated Flowchart**
   a. Recruitment beginning Spring 2016
   b. AUDIT scores > 6 men and >3 women OR one episode of binge drinking in past 3-months
   c. 3100 screen, 750 to enroll and randomized
   d. Subjects randomized to either :
      i. 30min Online/Smartphone Tailored Web-based Intervention Followed by twice weekly text/email messages x 1 month (n = 375) OR
      ii. Enhanced Usual Care (generic, non-tailored 2h Guard alcohol module completed annually) (n = 375)
   e. Primary Outcome: Reduced frequency, intensity, or binge drinking at 3-, 6-, & 12-months documented by 45 min follow up interviews (web, phone, or in-person) (80% retention; n = 600; 300/group) (n = 750)

5. **Study Progress**
   a. Collaboration with Case Western to develop protocol, procedures, finalization of measures
   b. Collaboration with the UM Center for Health, Communication and Research to identify the correct smart-phone technology
   c. Smartphone app development- meeting weekly to design the app
   d. Identification of key features to use with the smart phone technology
      i. Drinking tracker
      ii. Newsfeed
      iii. Asking an peer/expert
      iv. Weekly/Weekend planner
      v. Video peers
      vi. Tools/resources with links

6. **Successes and Lessons Learned**
   a. An e-health approach has great potential for overcoming the challenges with building resilience in reserve components – their part-time status and relative distance from brick and mortar military programs.
   b. During the initial intervention need to begin the process of setting up the continuous use of the app.
   c. Periodic assessment questions (texts), in plain language, that assess Concerns or progress on Goals and Strategies that the subject has identified in the initial set-up.
   d. Importance of leadership buy-in.
   e. Presented at state-wide OARNG leadership conference in March 2015.
   f. Received UM IRB approval.

7. **Current and Anticipated Challenges**
   a. Submit the DoD IRB, along with Case Western, UToledo and UM IRB approvals
   b. Meetings with Ohio National Guard Advisory Board to advise in app development

c. Continue to work with development team on smartphone features
d. Focus testing smartphone app features
e. Key challenges are engagement in and adherence to the intervention offered
f. Getting iOS and Android approval through the app store

An email summary outlining the status of the project over the past year was sent to the Scientific Advisory Board (SAB) members on 04 Mar 2016 since the SAB will not be occurring until later in 2016.

Task #5: Regulatory & Reporting – 42% completed
The protocol has been submitted to and approved by the University Hospitals IRB (UH IRB) and the University Of Michigan Medical School IRB. In addition, minor updates were submitted and approved by both the UH IRB and the University Of Michigan Medical School IRB. The University of Toledo Biomedical Institutional Review Board reviewed the submission on April 21, 2016 and requested some minor updates before giving final approval. These minor updates, along with the minor updates that were approved by the University Hospitals IRB and the University Of Michigan Medical School IRB, were submitted late August, 2016 and approval is pending.

UHCMC sent in their submission packet to USAMRMC Office of Research Protection Office on 14 Apr 2016. A request for changes to the Pre-Screening and Verbal Consent Script was received on 26 Jul 2016. Changes were made to this document and submitted to the UH IRB and University Of Michigan Medical School IRB. Once they are approved by the UH IRB, they will be submitted to the USAMRMC Office of Research Protection Office. The initial submission packet for UM, which included approval for the requested changes mentioned above, was sent to USAMRMC Office of Research Protection Office on 29 Aug 2016

What opportunities for training and professional development has the project provided?
This project has provided Brittany Brownrigg, Data Coordinator at Case Western Reserve University, with the opportunity to work on a large-scale, multi-site, USAMRAA funded study. . She has had the opportunity to work with collaborating sites to create a database and procedural manual to be utilized by participating sites. She will have the opportunity to train the UT personnel on the utilization of the database and continue to be integrally involved with the data collection throughout the project period.

How were the results disseminated to communities of interest?
Nothing to Report

What do you plan to do during the next reporting period to accomplish the goals?

Task #1: Customize Computer Intervention for National Guard (NG) population

Study staff will finish testing the app and CHCR will make the required updates based on study staff feedback. These updates will be submitted to the iPhone and Android app stores so the final app is ready for participants to download when the study starts.

Task #2: Data Collection
Over the next year, the University of Toledo plans to hire, study personnel for their site. In addition, the manual of procedures will be completed and all study personnel will be trained in the various components of the study. The data coordinator will provide training on data entry, responding to queries and the quality assurance process that will be used during the study. Recruitment of subjects and randomization will commence as soon as the app has been fully tested and the appropriate updates made and we have received approval from HRPO to begin recruiting. We expect to be in the field in Fall 2016.

Task #3: Data Dissemination
Nothing to Report

Task #4: Oversight Meetings
Over the next year, we plan to have an External Scientific Advisory Board (SAB) meeting, which is scheduled for November 6th-7th, 2016. In addition, we will hold an External Administrative Advisory Board Meeting (AAB) with members of the ONG leadership. Finally, Dr. Blow will attend the 2016 Substance Abuse IPR. Data Safety Monitoring Board Meetings will be held quarterly when subject recruitment commences.

Task #5: Regulatory & Reporting
Over the next reporting period, we will continue to submit quarterly financial and technical reports to USAMRAA as required. In addition, we wait to hear from the USAMRMC Office of Research Protections Human Research Protection Office regarding approval to begin enrollment.

4. **IMPACT:** Describe distinctive contributions, major accomplishments, innovations, successes, or any change in practice or behavior that has come about as a result of the project relative to:

What was the impact on the development of the principal discipline(s) of the project?
Nothing to report.

What was the impact on other disciplines?
Nothing to report.

What was the impact on technology transfer?
Nothing to report.

What was the impact on society beyond science and technology?
Nothing to report.

5. **CHANGES/PROBLEMS:** The Project Director/Principal Investigator (PD/PI) is reminded that the recipient organization is required to obtain prior written approval from the awarding agency Grants Officer whenever there are significant changes in the project or its direction. If not previously reported in writing, provide the following additional information or state, "Nothing to Report," if applicable:

Changes in approach and reasons for change
Noting to report

Actual or anticipated problems or delays and actions or plans to resolve them
Because we decided to revise the statement of work to change the intervention platform and because this revision required USAMRAA approval, we were not able to begin work on the project until March 2015. This lead to delays in the development of the intervention and app, as well as database creation and the hiring and training of staff, which rolled over to the current reporting period and has thus lead to a delay in recruitment.

Changes that had a significant impact on expenditures
Delaying the startup of the study impacted expenditures. The University of Toledo has delayed hiring staff until the training and recruitment commences.

Significant changes in use or care of human subjects, vertebrate animals, biohazards, and/or select agents
Noting to report

Significant changes in use or care of human subjects
Noting to report

Significant changes in use or care of vertebrate animals.
No activities involving the use or care of vertebrate animals will be performed to complete this project.

Significant changes in use of biohazards and/or select agents
No activities involving the use biohazards and/or select agents will be performed to complete this project.

6. **PRODUCTS:** List any products resulting from the project during the reporting period. If there is nothing to report under a particular item, state "Nothing to Report."

   - **Publications, conference papers, and presentations**
     Nothing to Report

   - **Books or other non-periodical, one-time publications.**
     Nothing to Report

   - **Other publications, conference papers, and presentations.**
     Nothing to report.

   - **Website(s) or other Internet site(s)**
     Nothing to Report

   - **Technologies or techniques**
     Project GUARD app

- **Inventions, patent applications, and/or licenses**
  Licenses to place Project GUARD app on iPhone and Android app stores

- **Other Products**
  Nothing to report.

7. PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS

What individuals have worked on the project?
Name: Joseph R. Calabrese, MD
Project Role: Principal Investigator
Researcher Identifier (e.g. ORCID ID): ERA Commons - jcalabrese
Nearest person month worked: 0.3 calendar months
Contribution to Project: Oversight of grant negotiations including submission of requested documents to the Contract Specialist; ongoing administration and oversight of all aspects of the Ohio Army National Guard Mental Health Initiative.

Name: Mary Beth Serrano, MA
Project Role: Project Manager
Researcher Identifier (e.g. ORCID ID): N/A
Nearest person month worked: 1.8 calendar months
Contribution to Project: Ms Serrano provided administrative support during this reporting period.

Name: Brittany Brownrigg, BS
Project Role: Data Coordinator
Researcher Identifier (e.g. ORCID ID): N/A
Nearest person month worked: 1.8 calendar months
Contribution to Project: Ms. Brownrigg provided data management support researching project tracking tools and working with the UH RedCap database team. She has created the database for the study and manual of procedures for use of the database. She has been involved in the review of the application.

Name: Nicole Moomaw, BA
Project Role: Research Coordinator II
Researcher Identifier (e.g. ORCID ID): N/A
Nearest person month worked: 5.16 calendar months
Contribution to Project: Ms. Moomaw has been responsible for the development of the IRB protocol and submission and preparing regulatory documents in addition to reviewing the assessments and database. She has created a manual of procedures and been involved in the review of the application.

Name: Carla Conroy
Project Role: Research Coordinator II
Researcher Identifier (e.g. ORCID ID): N/A

Nearest person month worked: 0.84 calendar months
Contribution to Project: Ms. Conroy has been responsible for the development of the IRB protocol and submission to the respective IRBs and HRPO as well as preparing regulatory documents across the sites. In addition, she has coordinated with the sites and provided feedback regarding the preparation of the app.

Name: John Wryobeck, PhD
Project Role: Co-investigator
Researcher Identifier (e.g. ORCID ID): n/a
Nearest Person Month: 3 calendar months annually
Contribution to Project: Dr.Wryobeck has been involved in creating the computer intervention program as well as survey.

Name: Frederic C. Blow, PhD
Project Role: Scientific Principal Investigator
Researcher Identifier (e.g. ORCID ID): ERA Commons - fredblow
Nearest person month worked: 3.0 calendar months
Contribution to Project: Dr. Blow has provided ongoing oversight of the initiative.

Name: Kristen Barry Haenchen, PhD
Project Role: Co-Investigator
Researcher Identifier (e.g. ORCID ID): ERA Commons - kbarry
Nearest person month worked: 1.6 calendar months
Contribution to Project: Dr. Haenchen began to develop intervention content for the mobile phone app.

Name: Lynn Massey, LMSW
Project Role: Project Manager
Research Identifier (e.g. ORCID ID): N/A
Nearest person month worked: 2.3 calendar months
Contribution to Project: Ms. Massey coordinated the meetings to design the development of the intervention app and has been working with the CHCR to develop components of the app.

Name: Rose Ignacio
Project Role: Data Manager/Analyst
Researcher Identifier (e.g. ORCID ID): N/A
Nearest person month worked: 2.0 calendar months
Contribution to Project: Ms. Ignacio worked on developing data dictionaries and data analytic plans during this reporting period.

Name: Mary Jannausch
Project Role: Data Manager/Analyst
Researcher Identifier (e.g. ORCID ID): N/A
Nearest person month worked: 3.6 calendar months
Contribution to Project: Ms. Jannausch worked on developing data dictionaries and data analytic plans during this reporting period.

Name: Holly Derry
Project Role: CHCR Staff
Researcher Identifier (e.g. ORCID ID): N/A
Nearest person month worked: 2.0 calendar months
Contribution to Project: Ms. Derry has been writing the content for the intervention app and working on app logic.

Name: Sarah Eustice
Project Role: CHCR Staff
Researcher Identifier (e.g. ORCID ID): N/A
Nearest person month worked: 2.6 calendar months
Contribution to Project: Ms. Eustice has been writing the content for the intervention app and working on app logic.

Name: Ian Moore
Project Role: CHCR Staff
Researcher Identifier (e.g. ORCID ID): N/A
Nearest person month worked: 4.8 calendar months
Contribution to Project: Mr. Moore has been writing code and designing the graphics for the app.

Name: Michael Nowak
Project Role: CHCR Staff
Researcher Identifier (e.g. ORCID ID): N/A
Nearest person month worked: 4.5 calendar months
Contribution to Project: Mr. Nowak has been writing code and designing the graphics for the app.

Name: Sophia Zhou
Project Role: CHCR Staff
Researcher Identifier (e.g. ORCID ID): N/A
Nearest person month worked: 2.3 calendar months
Contribution to Project: Ms. Zhou has been responsible for designing the Android app.

Name: David Pang
Project Role: CHCR Staff
Researcher Identifier (e.g. ORCID ID): N/A
Nearest person month worked: 3.0 calendar months
Contribution to Project: Mr. Pang has been responsible for the development of the Android app.

Name: Winnie Wong
Project Role: CHCR Staff
Researcher Identifier (e.g. ORCID ID): N/A
Nearest person month worked: 2.3 calendar months

Contribution to Project: Ms. Wong has been responsible for project management related to the development of the app.

Has there been a change in the active other support of the PD/PI(s) or senior/key personnel since the last reporting period?
Nothing to report

What other organizations were involved as partners?
Nothing to report.

8. **SPECIAL REPORTING REQUIREMENTS**

    COLLABORATIVE AWARDS: For collaborative awards, independent reports are required from BOTH the Initiating PI and the Collaborating/Partnering PI. A duplicative report is acceptable; however, tasks shall be clearly marked with the responsible PI and research site. A report shall be submitted to **https://ers.amedd.army.mil** for each unique award.

    Not applicable

    QUAD CHARTS: If applicable, the Quad Chart (available on https://www.usamraa.army.mil) should be updated and submitted with attachments.

    Quad Chart attached

Early Intervention to Reduce Alcohol Misuse and Abuse in the Ohio Army National Guard

Log Number: 13277015
Award Number: W81XWH-14-2-0007

PI: Joseph R. Calabrese, M.D   **Org:** Case Western Reserve University   **Award Amount:** $3,667,349

Study Aims

Specific Aims
1. Compare the MT-BI and EUC conditions in reducing the frequency and intensity of at-risk drinking at 3, 6, and 12 months post-intervention.
2. Compare the MT-BI and EUC conditions for binge drinking at 3-, 6- and 12 months

Secondary Aims
1. Compare the MT-BI and EUC conditions in reducing the frequency of illicit drug use and depressive symptoms at 3-, 6- and 12 months.
2. Examine the impact of the interaction of deployment status with intervention condition (MT-BI or EUC) on 3-, 6- and 12-month measures of alcohol and drug use
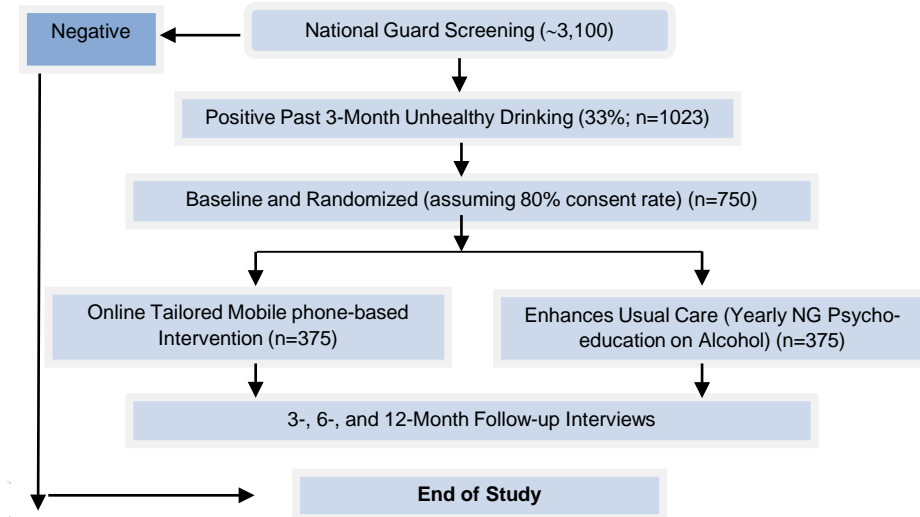
Approach

- The proposed project is a fully-powered randomized controlled trial of a mobile phone app - and text-based alcohol brief intervention (MT-BI) versus an Enhanced Usual Care (EUC) condition for National Guard members in the State of Ohio who meet criteria for unhealthy drinking in the previous 3 months.
- After tailoring the content of the MT- BI intervention for National Guard soldiers, the proposed study will screen ~ 3,100 different individuals over the three year enrollment period as part of the larger yearly ongoing longitudinal assessment of ONG members enrolled in the OHARNG MHI, to identify 750 participants with unhealthy drinking.
- These Guard members will then be randomized to either the MT-BI (n=375) or the EUC condition (n=375) and followed for one year post-enrollment.

Timeline and Cost

Activities CY	14-15	15-16	16-17	17-18	18-19
Customize Intervention/ App for National Guard (NG) population	███				
Data Collection		███			
Data Dissemination			███	███	███
Oversight Meetings		███	███	███	███
Estimated Budget	$1.1mil	$623K	$631K	$644K	$652K

Updated: 09/21/2016

Study Design Overview

Negative ← National Guard Screening (~3,100)

Positive Past 3-Month Unhealthy Drinking (33%; n=1023)

Baseline and Randomized (assuming 80% consent rate) (n=750)

Online Tailored Mobile phone-based Intervention (n=375)

Enhances Usual Care (Yearly NG Psycho-education on Alcohol) (n=375)

3-, 6-, and 12-Month Follow-up Interviews

End of Study

Work is underway on the design and development of the smartphone app, which is being developed for both the Android and iOS platforms. We are also working on completing the IRB submission for the CWRU site.

Goals/Milestones
CY14-15 Goals: ☑ Customize Intervention/App   ☑ Data Collection
☑ Oversight Meetings
CY15-16 Goals: ☑ Customize Intervention/App   ☐ Data Collection
☑ Oversight Meetings
CY16-17 Goals: ☐ Data Collection   ☐ Data Dissemination
☐ Oversight Meetings
CY17-18 Goals: ☐ Data Collection   ☐ Data Dissemination
☐ Oversight Meetings
CY18-19 Goals: ☐ Data Dissemination   ☐ Oversight Meetings
Comments/Challenges/Issues/Concerns
We are behind on our time line for intervention/app development, but plan to begin enrollment in the summer/fall. We plan to make up for the delay by enrolling subjects in to the study more quickly once the study begins.
Budget Expenditure to Date
Projected Expenditure: $1,282,902
Actual Expenditure: $859,945.52

9. APPENDICES

Early Intervention to Reduce Alcohol Misuse and Abuse in the Ohio Army National Guard

Coordinating PI: Joseph Calabrese, MD, Case Western Reserve
Scientific PI: Frederic Blow, PhD, Department of Veterans Affairs and University of Michigan

Award Number: W81XWH-14-2-0007
Award Period of Performance: 9/1/2014 – 8/31/2019
Total award: $3,667,349
Contract Officer: Dr. Ray Santullo
Project Officer: Dr. Carly Kiselycznyk

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M UNIVERSITY OF MICHIGAN

UH University Hospitals

Collaborators & Acknowledgements

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Ohio National Guard

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Captain Sephan Frazier

Ohio Army National Guard Mental Health Initiative—Primary Platform

Coordinating PI: **Joseph Calabrese, MD**
Scientific PI: **Sandro Galea, MD, DrPH**

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Columbia University MAILMAN SCHOOL OF PUBLIC HEALTH
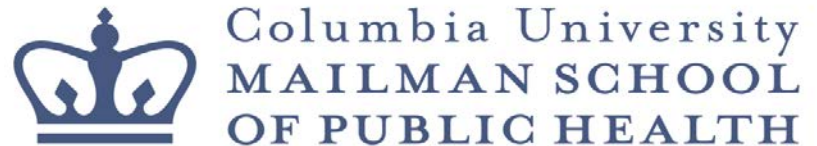
Co-PIs & Acknowledgements

Background & Rationale

Rationale

- •At-risk drinking, including binge drinking, is particularly common among reserve component members who have deployed to combat. Service members with at-risk drinking have an elevated risk for poor outcomes, including injuries, reduced job performance, mental health problems, and suicide.

- The existing military treatment infrastructure is likely to be insufficient to address the full range of needs of those with at-risk drinking, particularly for those in reserve components, and the SBIRT model provides an ideal opportunity to close this gap.

- The challenges of intervening with at-risk service members are likely to be magnified for NG troops who are geographically dispersed and must divide their time between military and civilian responsibilities.

Uniqueness

- •This project will directly address these critical issues by enlisting key OARNG personnel to inform the tailoring of a eHealth SBIRT approach to fit the needs of the NG and then test the impact of the intervention on at-risk drinking among NG soldiers.

AIM 1: Compare the Smartphone(SP)-BI and EUC conditions in reducing the frequency and intensity of at-risk drinking at 3, 6, and 12 months post-intervention.

- Hypothesis: Participants randomized to the SP-BI condition will report significantly fewer days/week drinking and fewer drinks/day than participants in the EUC condition at follow-ups.

AIM 2: Compare the SP-BI and EUC conditions for binge drinking at 3-, 6- and 12 months.

- Hypothesis: Participants randomized to the SP-BI condition will report significantly fewer binge drinking episodes compared to the EUC participants at follow-ups.

Secondary AIM 1: Compare the SP-BI and EUC conditions in reducing the frequency of illicit drug use and depressive symptoms at 3-, 6- and 12 months.

- Hypothesis: Participants randomized to the SP-BI condition will significantly reduce the frequency of illicit drug use compared to participants in the EUC condition.

Secondary AIM 2: Examine the impact of the interaction of deployment status with intervention condition (SP-BI or EUC) on 3-, 6- and 12-month measures of alcohol and drug use.

- Hypothesis: NG members who have been deployed in OEF/OIF/OND are expected to have higher risk of at-risk drinking compared to those who have not been deployed. We hypothesize that individuals who have been deployed will be less likely to change their drinking than those who have not been deployed. However, the web-based program will address individual concerns and issues related to deployment.

Design & Methodology

- Given the rapidly changing mobile health field, with dramatic increases in the use of smartphone technologies, we are developing and testing an eHealth mobile phone app for delivery of intervention content, and for providing real-time feedback and support for drinking goals. This real-time feedback component will provide a unique platform for delivery of intervention content and follow-ups.

- The smartphone mobile app will include a section on safe rides to prevent drinking and driving.

- One of the strengths of this project is that we will have access to detailed information collected in the longitudinal cohort that has been followed for several years, including extensive assessments that were conducted prior to and post-deployment (Calabrese; Ohio Army National Guard Mental Health Initiative). Thus, the Ohio-based DOD study will have the ability to examine moderators including impact of deployment and development of comorbid mental disorders
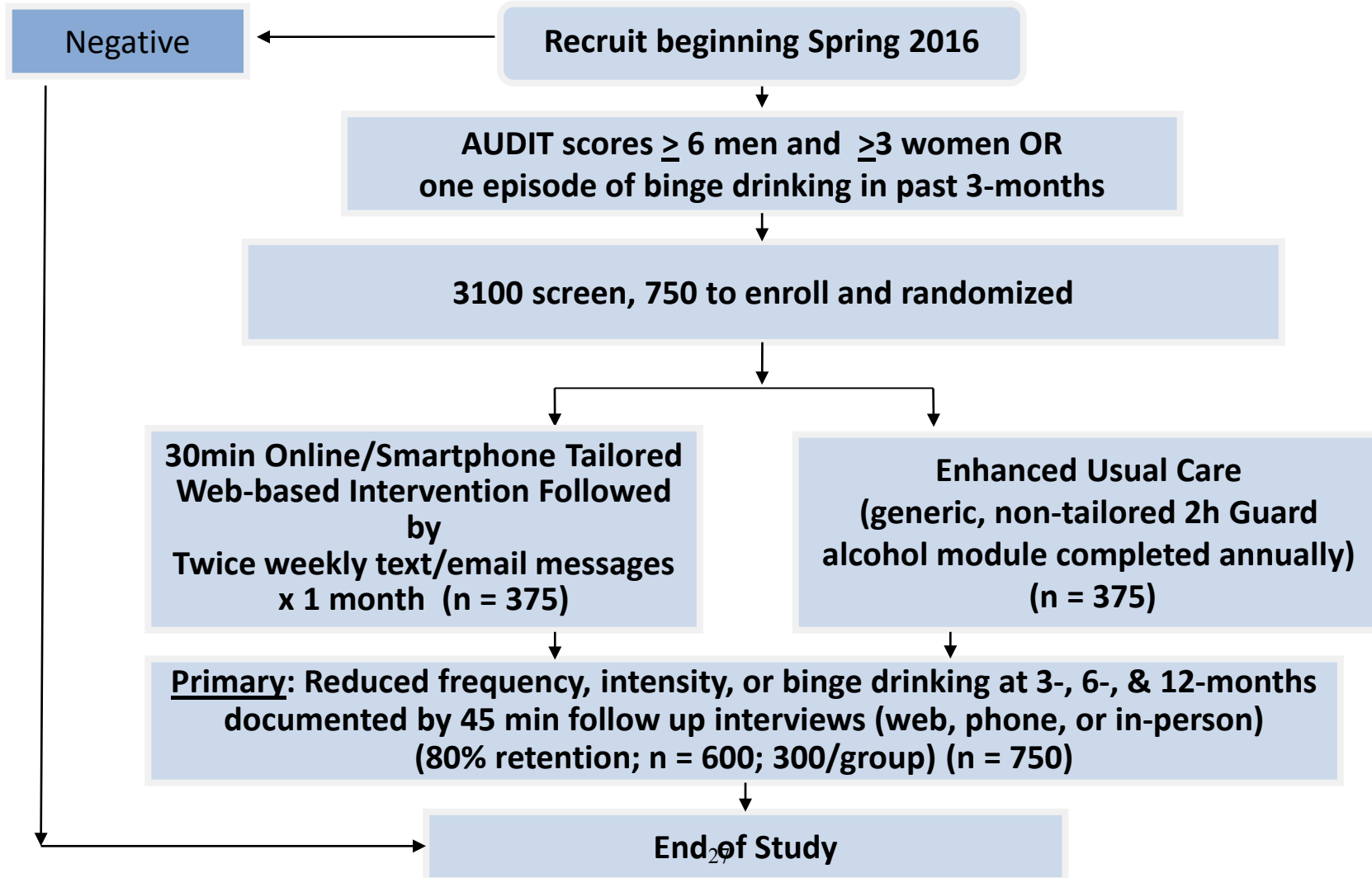
Methodology

- On a population basis, SBIRT approaches can have a meaningful impact on the hazardous use of alcohol and other substances.

- Engagement and adherence have been a limiting factor in previous attempts to apply population based approaches to hazardous use of alcohol and other substances, including in military populations.

- Smartphone apps have many advantages over other approaches:

  - Allows for and encourages frequent short interactions with the subject – the phone is in many ways an extension of the person and his/her social milieu – it is always there with you.

  - At all times a graphically appealing and simple dashboard of icons will be available, without any prompts. For example, for a particular subject who identified strategies to limit drinking (e.g. diluting drinks, alternating alcohol and non-alcohol drinks, setting a limit and sticking to it, etc.) there would be a "drinking strategies" icon on his dashboard.

Anticipated Flowchart

Recruit beginning Spring 2016

Negative

AUDIT scores ≥ 6 men and ≥3 women OR
one episode of binge drinking in past 3-months

3100 screen, 750 to enroll and randomized

30min Online/Smartphone Tailored
Web-based Intervention Followed by
Twice weekly text/email messages x 1 month (n = 375)

Enhanced Usual Care
(generic, non-tailored 2h Guard alcohol module completed annually)
(n = 375)

Primary: Reduced frequency, intensity, or binge drinking at 3-, 6-, & 12-months documented by 45 min follow up interviews (web, phone, or in-person) (80% retention; n = 600; 300/group) (n = 750)

End of Study

Study Progress

- Collaboration with Case Western to develop protocol, procedures, finalization of measures
- Collaboration with the UM Center for Health, Communication and Research to identify the correct smart-phone technology
- Smartphone app development- meeting weekly to design the app
- Identification of key features to use with the smart phone technology
  - Drinking tracker
  - Newsfeed
  - Asking an peer/expert
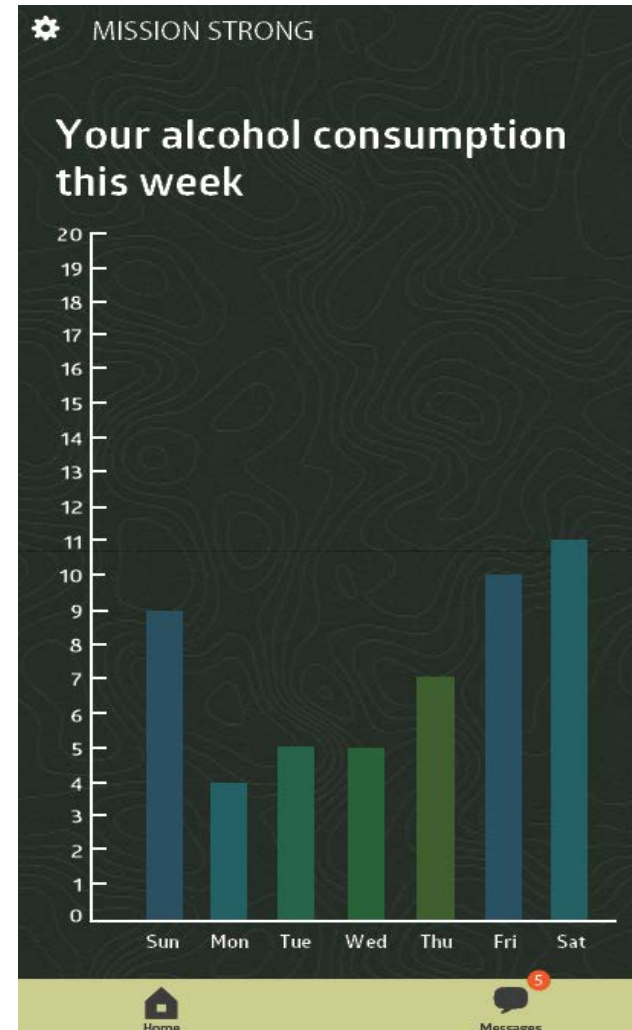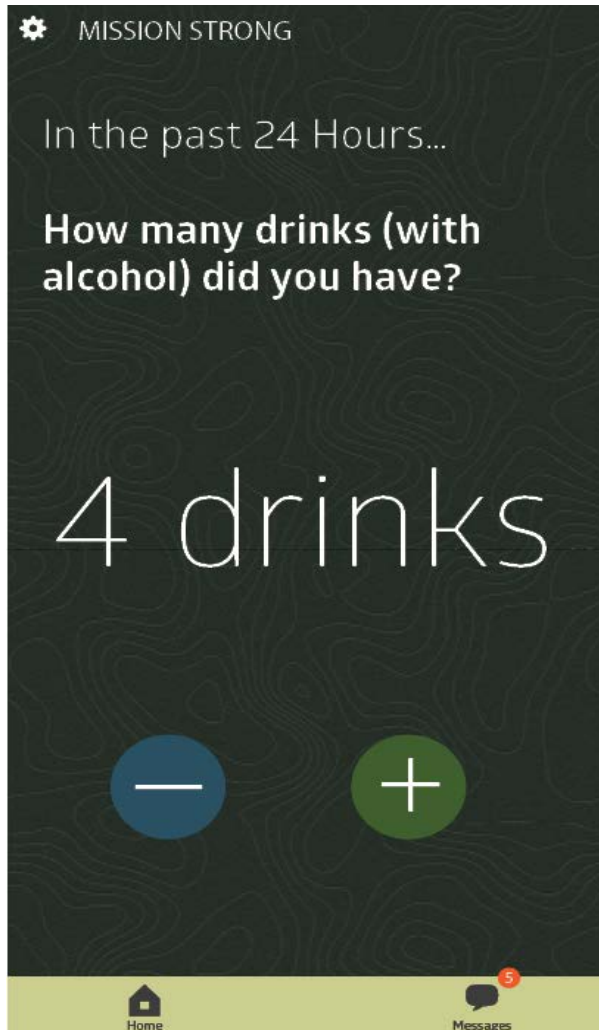 - Weekly/Weekend planner
  - Video peers
  - Tools/resources with links
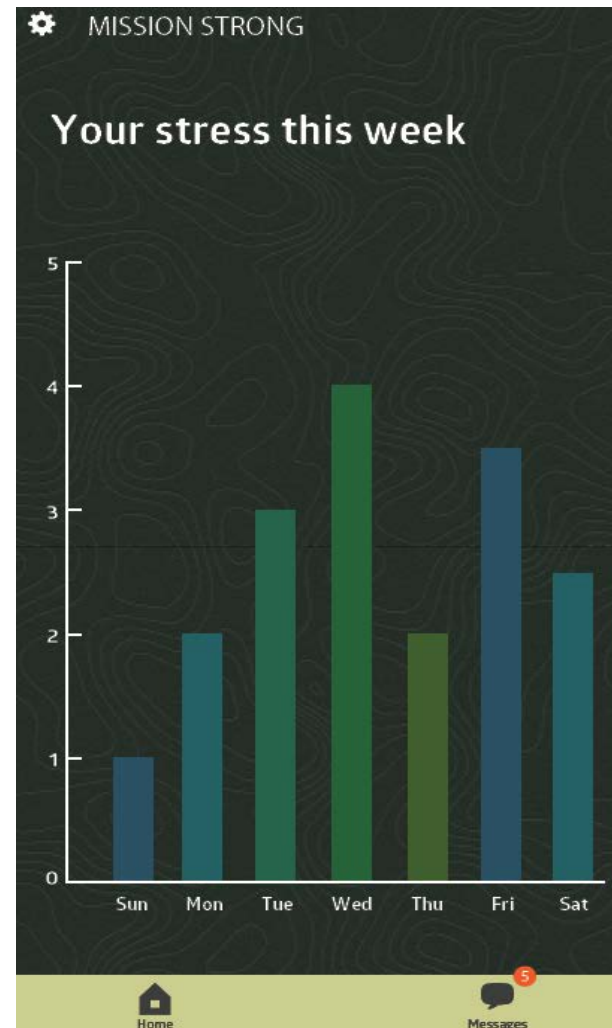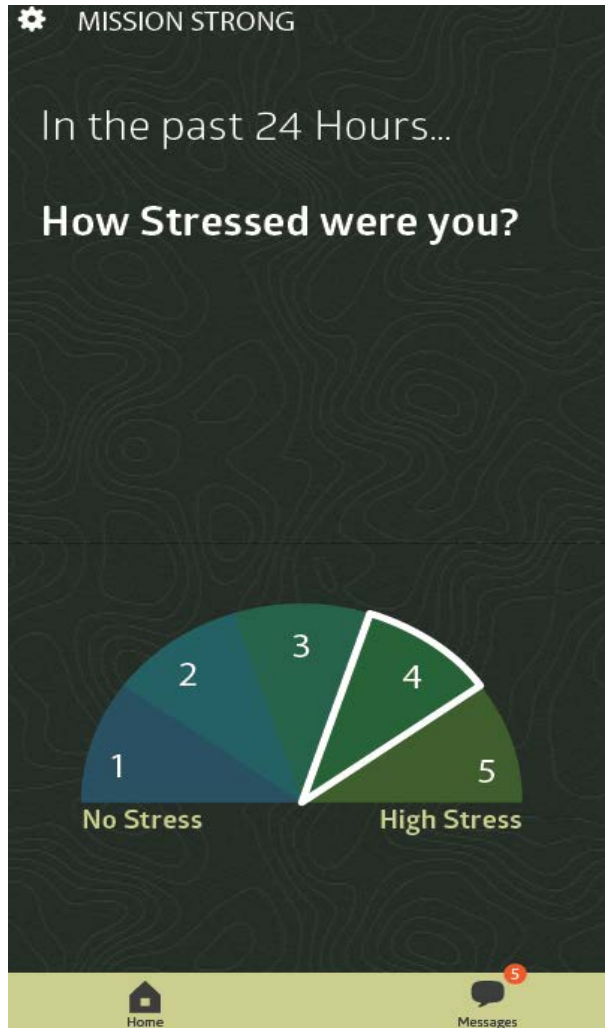
Screen Shots of Smartphone App
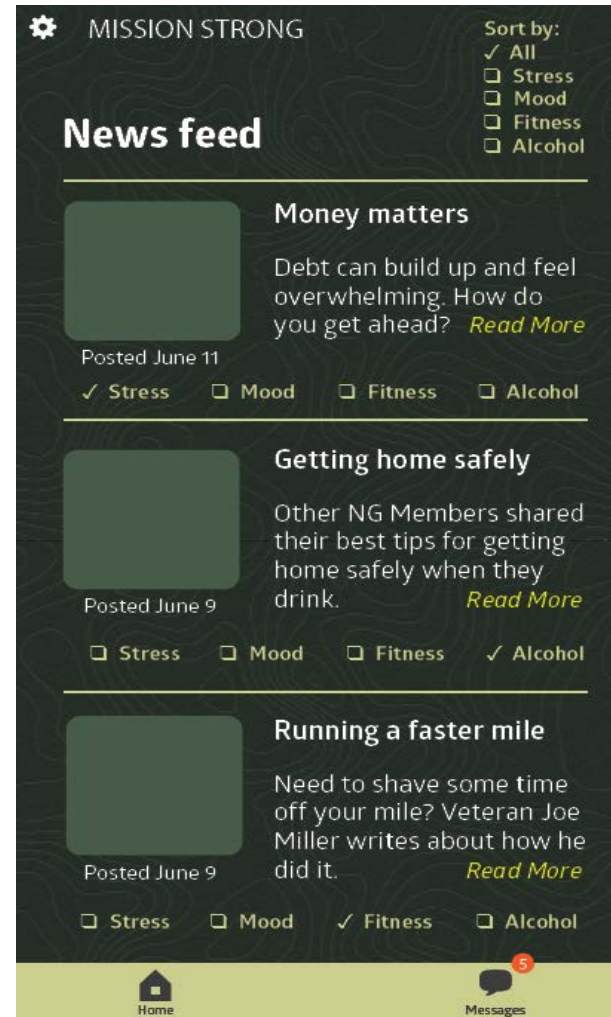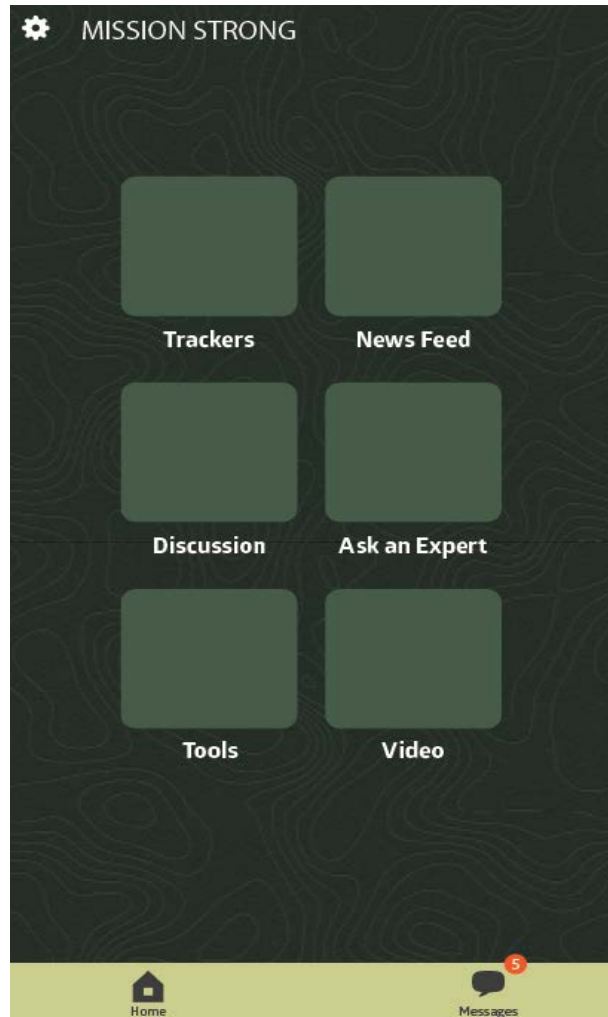
Screen Shots of Alcohol Tracker

Screen Shots of Stress Tracker

Successes and Lessons Learned

- An e-health approach has great potential for overcoming the challenges with building resilience in reserve components – their part-time status and relative distance from brick and mortar military programs.

- During the initial intervention need to begin the process of setting up the continuous use of the app.

- Periodic assessment questions (texts), in plain language, that assess Concerns or progress on Goals and Strategies that the subject has identified in the initial set-up.

- Importance of leadership buy-in.

- Presented at state-wide OARNG leadership conference in March 2015.

- Received UM IRB approval.

Current and Anticipated Challenges

- Submit the DoD IRB, along with Case Western, UToledo and UM IRB approvals

- Meetings with Ohio National Guard Advisory Board to advise in app development

- Continue to work with development team on smartphone features

- Focus testing smartphone app features

- Key challenges are engagement in and adherence to the intervention offered

- Getting iOS and Android approval through the app store